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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,149	10/19/2001	R. Preston Mason	2189 P01 US CIP	2552
26486	7590	06/03/2004	EXAMINER	
PERKINS, SMITH & COHEN LLP ONE BEACON STREET 30TH FLOOR BOSTON, MA 02108			JIANG, SHAOJIA A	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

10/033,149

Applicant(s)

MASON, R. PRESTON

Examiner

Shaojia A Jiang

Art Unit

1617

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

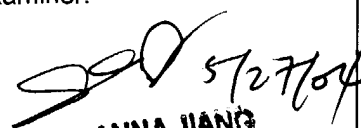
Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 1-14, 22-28, 57-59 and 63-65.

Claim(s) withdrawn from consideration: 29-56 and 60-62.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____


SHAOJIA ANNA JIANG
PATENT EXAMINER

Advisory Action

This Office Action is a response to Applicant's proposed amendment and response after FINAL filed on May 3, 2004.

Applicant's declarations under 37 CFR 1.132 of Dr. R. Preston Mason (inventor), and Dr. J. Wouter Jukema (not inventor), submitted after FINAL May 3, 2004, will not be entered and considered since these declarations are not considered filed timely. See MPEP 716.01.

2. Applicant's proposed amended claims herein, changing limitation and the scope of claims, i.e., inserting a new limitation into the independent claim 1, adding new claims, present a new issue for search and consideration by the Examiner.

Therefore, the proposed amendment After Final will not be entered.

5. The rejection of Claims 1-14, 22-28, 57-59 and 63-65 made under 35 U.S.C. 103(a) as being unpatentable over Davidson et al. (4,879,303) and Bjorge et al. (5,385,929) in view of Jekema et al. (Arteriosclerosis, Thrombosis, and Vascular Biology, Vol. 16, No.3, 1996, p425-430), and Merck Index, for reasons of record stated in the Final Office Action dated January 29, 2004, is maintained.

Applicant's remarks filed May 3, 2004 with respect to this rejection in the Final Office Action dated January 29, 2004 have been fully considered but are unpersuasive for reasons of record stated in the Final Office Action.

Additionally, the declarations of Dr. R. Preston Mason and Dr. J. Wouter Jukema under 37 CFR 1.132 are insufficient to establish the fact that the claimed combination

Art Unit: 1617

has unexpected synergism, since first, the results in Figure 1 and 2 lack of factual data showing how these experiments and testing were conducted, and how these results were obtained, e.g., it is unclear whether testing in vitro or vivo, and what specific effective amounts of the combination of amlodipine and what specific and particular hydroxylated atorvastatin metabolite were tested. Moreover, it is noted that the declarations provide no clear side-by-side comparison with the closest prior art, i.e., comparing with Jekema et al., in support of nonobviousness for the instant claimed invention over the prior art.

Applicant has the burden to explain the experimental evidence. See *In re Borkowski and Van Venrooy* 184 USPQ 29 (CCPA 1974). Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

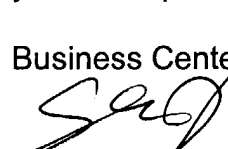
For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang whose telephone number is 571.272.0627. The examiner can normally be reached on 9 am -5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571.272.0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
May 27, 2004